

COPY

PTO-1449 REPRODUCED SECOND SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 2, 2003 (Use several sheets if necessary)		ATTORNEY DOCKET NO. 2685.1003-008		APPLICATION NO. 09/822,716	
		APPLICANT David A. Edwards, et al.			
		FILING DATE March 30, 2001		CONFIRMATION NO. 7248	GROUP 1615
U.S. PATENT DOCUMENTS					
EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME	
M	BA	2,470,296	05/17/49	Fields	
	BB	2,533,065	12/05/50	Taplin et al.	
	BC	2,992,645	07/18/61	Fowler	
	BD	3,781,230	12/25/73	Vassiliades et al.	
	BE	3,957,965	05/18/76	Harley et al.	
	BF	4,009,280	02/22/77	Macarthur et al.	
	BG	4,089,800	05/16/78	Temple	
	BH	4,161,516	07/17/79	Bell	
	BI	4,173,488	11/06/79	Vassiliades et al.	
	BJ	4,272,398	06/09/81	Jaffe	
	BK	4,352,883	10/05/82	Lim	
	BA2	4,391,909	07/05/83	Lim	
	BB2	4,466,442	08/21/84	Hilman et al.	
	BC2	4,480,041	10/30/84	Myles et al.	
	BD2	4,524,769	06/25/85	Wetterlin	
	BE2	4,572,203	02/25/86	Feinstein	
	BF2	4,590,206	05/20/86	Forrester et al.	
	BG2	4,615,697	10/07/86	Robinson	
	BH2	4,679,555	07/14/87	Sackner	
	BI2	4,741,872	05/03/88	De Luca et al.	
	BJ2	4,743,545	05/10/88	Torobin	
	BK2	4,774,958	10/04/88	Feinstein	
	BA3	4,789,550	12/06/88	Hommel et al.	
	BB3	4,818,542	04/04/89	De Luca et al.	
	BC3	4,847,091	07/11/89	Illum	
	BD3	4,855,144	08/08/89	Leong et al.	
✓	BE3	4,857,311	08/15/89	Domb et al.	
EXAMINER			DATE CONSIDERED 2/12/04		

PTO-1449 REPRODUCED

**SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
M	BF3	4,861,627	08/29/89	Mathiowitz et al.
M	BG3	4,865,789	09/12/89	Castro et al.
	BH3	This reference number intentionally left blank		
M	BI3	4,904,479	02/27/90	Illum
	BJ3	4,917,119	04/17/90	Potter et al.
	BK3	4,963,297	10/16/90	Madden
	BA4	4,976,968	12/11/90	Steiner
M	BB4	4,994,281	02/19/91	Muranishi et al.
	BC4	This reference number intentionally left blank		
M	BD4	5,033,463	07/23/91	Cocozza
	BE4	5,064,650	11/12/91	Lew
	BF4	5,069,936	12/03/91	Yen
	BG4	5,075,109	12/24/91	Tice et al.
	BH4	5,100,669	03/31/92	Hyon et al.
	BI4	5,123,414	06/23/92	Unger
	BJ4	5,145,684	09/08/92	Liversidge et al.
	BK4	5,160,745	11/03/92	De Luca et al.
	BA5	5,169,871	12/08/92	Hughes et al.
	BB5	5,174,988	12/29/92	Mautone et al.
	BC5	5,195,520	03/23/93	Schlieff et al.
	BD5	5,204,108	04/20/93	Illum
	BE5	5,204,113	04/20/93	Hartley et al.
	BF5	5,260,306	11/09/93	Boardman et al.
	BG5	5,271,961	12/21/93	Mathiowitz et al.
	BH5	5,306,483	04/26/94	Mautone
✓	BIS	5,327,883	07/12/94	Williams et al.

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
M	BJ5	5,334,381	08/02/94	Unger
	BK5	5,340,587	08/23/94	Milhalko et al.
	BA6	5,352,435	10/04/94	Unger
	BB6	5,384,133	01/24/95	Boyes et al.
	BC6	5,393,524	02/28/95	Quay
	BD6	5,407,609	04/18/95	Tice et al.
	BE6	5,456,917	10/10/95	Wise et al.
	BF6	5,466,841	11/14/98	Horrobin et al.
	BG6	5,482,946	01/09/96	Clark et al.
	BH6	5,518,709	05/21/96	Sutton et al.
	BI6	5,518,998	05/21/96	Bäckström et al.
	BJ6	5,551,489	09/03/96	Trofast et al.
	BK6	5,580,575	12/03/96	Unger et al.
	BA7	5,607,695	03/04/97	Ek et al.
	BB7	5,607,915	03/04/97	Patton
	BC7	5,612,053	03/18/97	Baichwal et al.
	BD7	5,614,216	03/25/97	Janoff
	BE7	5,654,007	08/05/97	Johnson
	BF7	5,690,954	11/25/97	Illum
	BG7	5,698,721	12/16/97	Heath
	BH7	5,707,644	01/13/98	Illum
	BI7	5,709,884	01/20/98	Trofast et al.
	BJ7	5,780,014	07/14/98	Eljamal
	BK7	5,795,594	08/18/98	York et al.
	BA8	5,804,212	09/08/98	Illum
✓	BB8	5,814,607	09/29/98	Patton

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-008		APPLICATION NO. 09/822,716	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 2, 2003 (Use several sheets if necessary)		APPLICANT David A. Edwards, et al.			
		FILING DATE March 30, 2001		CONFIRMATION NO. 7248	
U.S. PATENT DOCUMENTS					
EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME	
M	BC8	5,830,853	11/03/98	Bäckström, et al.	
M	BD8	5,851,453	12/22/98	Hanna, et al.	
	BE8	This reference number intentionally left blank			
M	BF8	5,874,063	02/23/99	Briggner et al.	
	BG8	This reference number intentionally left blank			
M	BH8	5,885,613	03/23/99	Holland et al.	
I	BI8	5,902,802	05/11/99	Heath	
I	BJ8	5,922,354	07/13/99	Johnson	
M	BK8	5,928,469	07/27/99	Franks et al.	
	BA9	This reference number intentionally left blank			
	BB9	This reference number intentionally left blank			
	BC9	This reference number intentionally left blank			
M	BD9	5,993,783	11/30/99	Eljamal	
	BE9	This reference number intentionally left blank			
	BF9	This reference number intentionally left blank			
	BG9	This reference number intentionally left blank			
M	BH9	6,019,968	02/01/00	Platz	
	BI9	This reference number intentionally left blank			
M	BJ9	6,051,256	04/18/00	Platz	
M	BK9	6,063,138	05/16/00	Hanna et al.	
	BA10	This reference number intentionally left blank			
M	BB10	6,080,721	06/27/00	Patton	
	BC10	This reference number intentionally left blank			
EXAMINER <i>M</i>			DATE CONSIDERED 2/12/04		

PTO-1449 REPRODUCED

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
M	BL	WO 80/02365	13/11/80	PCT			
	BM	WO 86/06959	04/12/86	PCT			
	BN	WO 88/04556	30/06/88	PCT			
	BO	WO 88/09163	01/12/88	PCT			
	BP	WO 91/04732	18/04/91	PCT			
	BQ	WO 91/06286	16/05/91	PCT			
	BL2	WO 91/06287	16/05/91	PCT			
m	BM2	WO 91/12823	05/09/91	PCT			
	BN2	This reference number intentionally left blank					
M	BO2	WO 92/18164	29/10/92	PCT			
	BP2	WO 92/21382	10/12/92	PCT			
	BQ2	WO 93/25221	23/12/93	PCT			
	BL3	WO 94/04133	03/03/94	PCT			
	BM3	WO 94/07514	14/04/94	PCT			
	BN3	WO 94/08627	28/04/94	PCT			
	BO3	WO 94/16739	04/08/94	PCT			
	BP3	WO 95/00127	05/01/95	PCT			
	BQ3	WO 95/07072	16/03/95	PCT			
	BL4	WO 95/24183	14/09/95	PCT			
	BM4	WO 95/31479	23/11/95	PCT (Platz)			
	BN4	WO 95/35097	28/12/95	PCT			
m	BO4	WO 96/09814	04/04/96	PCT			
	BP4	This reference number intentionally left blank					
m	BQ4	WO 96/23485	08/08/96	PCT			
	BL5	WO 96/32096	17/10/96	PCT (Eljamal)			
	BMS	WO 96/32116	17/10/96	PCT (Eljamal)			
✓	BN5	WO 96/32149	17/10/96	PCT (Platz)			
EXAMINER <i>[Signature]</i>				DATE CONSIDERED 2/12/04			

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

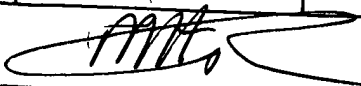
APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION
NO.
7248

GROUP
1615

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
M	BO5	WO 96/40963	19/12/96	PCT			
	BP5	WO 96/41873	27/12/96	PCT			
	BQ5	WO 97/03649	06/02/97	PCT			
M	BL6	WO 97/36574	09/10/97	PCT			
	BM6	This reference number intentionally left blank					
M	BN6	WO 98/16205	23/04/98	PCT (Foster)			
	BO6	WO 98/29096	09/07/98	PCT (Gordon)			
	BP6	WO 98/29098	09/07/98	PCT (Gordon)			
	BQ6	WO 98/29140	09/07/98	PCT (Gordon)			
M	BL7	WO 98/29141	09/07/98	PCT (Gordon)			
	BM7	This reference number intentionally left blank					
M	BN7	WO 98/51278	19/11/98	PCT			
	BO7	WO 99/16419	08/04/99	PCT			
	BP7	WO 99/16420	08/04/99	PCT			
	BQ7	WO 99/16421	08/04/99	PCT			
	BL8	WO 99/16422	08/04/99	PCT			
M	BM8	WO 99/66903	29/12/99	PCT			
	BN8	This reference number intentionally left blank					
M	BO8	WO 00/15262	23/03/00	PCT (Clark)			
	BP8	WO 00/21594	20/04/00	PCT (Clark)			
	BQ8	WO 00/33811	15/06/00	PCT			
	BL9	WO 01/00312 A1	04/01/01	PCT (Bennett)			
	BM9	WO 01/13891 A3	01/03/01	PCT			
M	BN9	WO 01/32144 A1	10/05/01	PCT (Lechuga- Ballesteros)			
EXAMINER				DATE CONSIDERED			
				2/12/04			

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	NO
<i>M</i>	BO9	WO 02/09669 A3	07/02/00	PCT (Snyder)				
	BP9	WO 02/11695 A3	14/02/02	PCT (Stevenson)				
	BQ9	WO 02/054868 A2	18/07/02	PCT (Weickert)				
	BL10	WO 02/055101 A2	18/07/02	PCT (Hastedt)				
	BM10	WO 02/087542 A1	07/11/02	PCT (Bot)				
	BN10	EP 0 072 046 A1	16/02/03	EPO				
	BO10	EP 0 213 303 B1	04/09/91	EPO				
	BP10	EP 0 257 915 A1	02/03/88	EPO				
	BQ10	EP 0 257 956 B1	20/05/92	EPO				
	BL11	EP 0 324 938 A1	26/07/89	EPO				
	BM11	EP 0 335 133 A2	04/10/89	EPO				
	BN11	EP 0 458 745 A1	14/05/91	EPO				
	BO11	EP 0 510 731 A1	28/10/92	EPO				
	BP11	EP 0 634 166 A1	18/01/95	EPO				
	BQ11	EP 0 656 206 A1	07/06/95	EPO				
	BL12	1 288 583	17/11/69	GB				
	BM12	1,300,009	05/05/92	Canada				
	BN12	1,302,258	02/06/92	Canada				
	BO12	2,058,428	05/09/00	Canada				
	BP12	2,085,884	30/12/91	Canada				
	BQ12	2,111,002	22/08/00	Canada				
	BL13	2,126,244	26/09/00	Canada				
	BM13	2,166,108	05/01/95	Canada				
✓	BN13	2,170,394	02/03/95	Canada				

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- | | |
|-------|--|
| BR | This reference number intentionally left blank. |
| M BS | Adjei, A., and Garren, J., "Pulmonary Delivery of Peptide Drugs: Effect of Particle Size on Bioavailability of Leuprolide Acetate in Healthy Male Volunteers," <i>Pharm. Res.</i> , 7(6):565-569 (1990). |
| BT | Allen, T.M., et al., "Subcutaneous Administration of Liposomes: A Comparison with the Intravenous and Intraperitoneal Routes of Injection," <i>Biochem. et Biophys. Acta.</i> 1150:9-16 (1993). |
| BU | Altshuler, B., et al., "Aerosol Deposition in the Human Respiratory Tract," <i>Am. Med. Assoc. Arch. of Indust. Health</i> 15:293-303 (1957). |
| BV | Anderson, P.J., et al., "Effect of Cystic Fibrosis on Inhaled Aerosol Boluses," <i>Am. Rev. Respir. Dis.</i> , 140:1317-1324 (1989). |
| BW | Anderson, M., et al., "Human Deposition and Clearance of 6- μ m Particles Inhaled with an Extremely Low Flow Rate," <i>Exp. Lung Res.</i> , 21:187-195 (1995). |
| BX | Barrera, D.A., et al., "Synthesis and RGD Peptide Modification of a New Biodegradable Copolymer: Poly(lactic acid-co-lysine)," <i>J. Am. Chem. Soc.</i> , 115:11010-11011 (1993). |
| BY | Beck, L.R., et al., "A New Long-Acting Injectable Microcapsule System for the Administration of Progesterone," <i>Fertility and Sterility</i> , 31(5):545-551 (1979). |
| BZ | Benita, S., et al., "Characterization of Drug-loaded Poly(d,l-lactide) Microspheres," <i>J. of Pharm. Sci</i> 73(12):1721-1724 (1984). |
| BR2 | Blackett, P.M., and G. Buckton, "A Microcalorimetric Investigation of the Interaction of Surfactants with Crystalline and Partially Crystalline Salbutamol Sulphate in a Model Inhalation Aerosol System," <i>Pharmaceutical Research</i> , 12(11):1689-1693 (1995). |
| BS2 | Brain, J.D., "Physiology and Pathophysiology of Pulmonary Macrophages". In <i>The Reticuloendothelial System</i> , Reichard and Filkins, eds. (Plenum Press, New York), pp. 315-327 (1985). |
| BT2 | Brown, A.R., et al., "Propellant-Driven Aerosols of Functional Proteins as Potential Therapeutic Agents in the Respiratory Tract," <i>Immunopharmacology</i> , 28:241-257 (1994). |
| BU2 | Byron, P.R., "Determinants of Drug and Polypeptide Bioavailability from Aerosols Delivered to the Lung," <i>Adv. Drug. Del. Rev.</i> , 5:107-132 (1990). |
| BV2 | Carroll, B.A., et al., "Gelatin Encapsulated Nitrogen Microbubbles as Ultrasonic Contrast Agents," <i>Investigative Radiology</i> , 15:260-266 (1980). |
| BW2 | Carroll, B.A., et al., "Ultrasonic Contrast Enhancement of Tissue by Encapsulated Microbubbles," <i>Radiology</i> , 143:747-750 (1982). |
| M BX2 | Ch'ng, H.S., et al., "Bioadhesive Polymers as Platforms for Oral Controlled Drug Delivery II: Synthesis and Evaluation of Some Swelling, Water-Insoluble Bioadhesive Polymers," <i>J. of Pharm Sci.</i> , 74(4):399-405 (1985). |

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-008	APPLICATION NO. 09/822,716	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 2, 2003 (Use several sheets if necessary)		APPLICANT David A. Edwards, et al.		
		FILING DATE March 30, 2001	CONFIRMATION NO. 7248	GROUP 1615
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
M	BY2	Clark, A., and P. Byron, "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank. Atm.org.</i> , 166:13-24 (1986).		
	BZ2	Clark, A.R., and M. Egan, "Modeling the Deposition of Inhaled Powdered Drug Aerosols," <i>J. Aerosol Sci.</i> , 25(1):175-186 (1994).		
	BR3	Clay, M.M., et al. "Effect of Aerosol Particle Size on Bronchodilatation with Nebulised Terbutaline in Asthmatic Subjects," <i>Thorax</i> 41:364-368 (1986).		
	BS3	Cohen, S., et al., "Controlled Delivery Systems for Proteins Based on Poly(Lactic/Glycolic Acid) Microspheres," <i>Pharm. Res.</i> 8(6):713-720 (1991).		
	BT3	Colthorpe, P., et al., "The Pharmacokinetics of Pulmonary-Delivered Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit," <i>Pharm. Res.</i> 9(6):764-768 (1992).		
	BU3	Daly, W.H., et al., "The Preparation of N-Carboxyanhydrides of α -Amino Acids Using Bis(Trichloromethyl) Carbonate," <i>Tetrahedron Lett.</i> , 29(46):5859-5862 (1988).		
	BV3	Damms, B. and W. Bains, "The Cost of Delivering Drugs without Needles," <i>J. Controlled Release</i> , 8-11 (1996).		
	BW3	Darquenne, C., and M. Paiva, "Two and Three-Dimensional Simulations of Aerosol Transport and Deposition in Alveolar Zone of Human Lung," <i>Journal of Applied Physiology</i> , 80(4):1401-1414 (1996).		
	BX3	Davies, C.N., et al., "Breathing of Half-micron Aerosols. I. Experimental.," <i>J. of Appl. Physiol.</i> 32(5):591-600 (1972).		
	BY3	Davis, S.S., and L. Illum, "Polymeric Microspheres as Drug Carriers," <i>Biomaterials</i> , 9:111-115 (1988).		
	BZ3	Davis, S.S., et al., "Microspheres as Controlled-Release Systems for Parenteral and Nasal Administration," <i>Controlled Release Technology</i> , Chapter 15, pp. 201-213 (1987).		
M	BR4	Dorries, A.M., and Valberg P.A., "Heterogeneity of Phagocytosis for Inhaled Versus Instilled Material," <i>Am. Rev. Respir. Dis.</i> , 146:831-837 (1992).		
	BS4	This reference number intentionally left blank.		
	BT4	This reference number intentionally left blank.		
M	BU4	Eldridge, J. H.; et al., "Biodegradable Microspheres as a Vaccine Delivery System," <i>Mol. Immunol.</i> , 28(3):287-294 (1991).		
	BV4	Feinstein, S.B., et al., "Two-Dimensional Contrast Echocardiography I. In Vitro Development and Quantitative Analysis of Echo Contrast Agents," <i>JACC</i> 3(1):14-20 (1984).		
↓	BW4	Ferin, J., et al., "Pulmonary Retention of Ultrafine and Fine Particles in Rats," <i>Am. J. Respir. Cell Mol. Biol.</i> 6:535-542 (1992).		
EXAMINER		DATE CONSIDERED 2/12/04		

PTO-1449 REPRODUCED

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M	BX4	Findeisen, W. "Über Das Absetzen Kleiner, in Der Luft Suspenderter Teilchen in Der Menschlichen Lunge Bei Der Atmung," <i>Pflugers Arch. D. Ges. Physiol.</i> 236:367-379 (1935).
	BY4	This reference number intentionally left blank.
M	BZ4	Ganderton, D., "The Generation of Respirable Clouds Form Coarse Powder Aggregates," <i>J. Biopharmaceutical Sciences</i> , 3(1/2):101-105 (1992).
M	BR5	Gehr, P. et al., "Surfactant and Inhaled Particles in the Conducting Airways: Structural, Stereological, and Biophysical Aspects," <i>Microscopy Res. And Tech.</i> , 26:423-436 (1993).
M	BS5	Gerrity, T.R., et al., "Calculated Deposition of Inhaled Particles in the Airway Generations of Normal Subjects," <i>J. Appl. Phys.</i> , 47(4):867-873 (1979).
	BT5	This reference number intentionally left blank.
M	BU5	Gonda, I., "Preface. Major Issues and Future Prospects in the Delivery of Therapeutic and Diagnostic Agents to the Respiratory Tract," <i>Adv. Drug Del. Rev.</i> 5:1-9 (1990).
	BV5	This reference number intentionally left blank.
M	BW5	Gonda, I., "Targeting by Deposition," in <i>Pharmaceutical Inhalation Aerosol Technology</i> (ed. A.J. Hickey), Marcel Dekkar Inc., pp. 61-82, New York (1992).
M	BX5	Gurny, R., et al., "Bioadhesive Intraoral Release Systems: Design, Testing and Analysis," <i>Biomaterials</i> , 5:336-340 (1984).
	BY5	This reference number intentionally left blank.
	BZ5	This reference number intentionally left blank.
M	BR6	Heyder, J., and G. Rudolf, "Mathematical models of particle deposition in the human respiratory tract," <i>J. Aerosol Sci.</i> , 15:697-707 (1984).
	BS6	Heyder, J., et al., "Total Deposition of Aerosol Particles in the Human Respiratory Tract for Nose and Mouth Breathing," <i>J. Aerosol Sci.</i> , 6:311-328 (1975).
	BT6	Hickey, A.J., et al., "Use of Particle Morphology to Influence the Delivery of Drugs from Dry Powder Aerosols," <i>J. Biopharmaceutical Sci.</i> , 3(1/2):107-113 (1992).
	BU6	Hirano, S., et al., "Pulmonary Clearance and Toxicity of Zinc Oxide Instilled into the Rat Lung," <i>Arch. of Toxicology</i> , 63:336-342 (1989).
✓	BV6	Hrkach, et al., "Synthesis of Poly(L-lactic acid-co-L-lysine) Graft Copolymers," <i>Macromolecules</i> , 28(13):4736-4739 (1995).

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-008	APPLICATION NO. 09/822,716	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 2, 2003 (Use several sheets if necessary)		APPLICANT David A. Edwards, et al.		
		FILING DATE March 30, 2001	CONFIRMATION NO. 7248	GROUP 1615
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
M	BW6	Hrkach, J.S., et al., "Poly(L-Lactic acid-co-amino acid) Graft Copolymers: A Class of Functional Biodegradable Biomaterials" in Hydrogels and Biodegradable Polymers for Bioapplications, ACS Symposium Series No. 627, Raphael M. Ottenbrite, et al., Eds., Americal Chemical Society, Chapter 8, pp. 93-101, 1996.		
	BX6	Illum, L., et al., "Bioadhesive Microspheres as a Potential Nasal Drug Delivery System," <i>Int. J. of Pharm.</i> 39:189-199 (1987).		
	BY6	Johnson, M.A., et al. "Delivery of Albuterol and Ipratrophiumbromide from Two Nebulizer Systems in Chronic Stable Asthma: Efficacy and Pulmonary Deposition," <i>Chest</i> , 96:6-10 (1989).		
	BZ6	Kao, Y.J., and R.L. Juliano, "Interactions of Liposomes with the Reticuloendothelial System, Effects of Reticuloendothelial Blockade on the Clearance of Large Unilamellar Vesicles," <i>Biochimica et Biophys. Acta.</i> 677:453-461 (1981).		
M	BR7	Kassem, N.M., and D. Ganderton, "The Influence of Carrier Surface on the Characteristics of Inspirable Powder Aerosols," <i>J. Pharm. Pharmacol.</i> , 42(Supp):11 (1990).		
	BS7	This reference number intentionally left blank.		
M	BT7	Kobayashi, S. et al., "Pulmonary Delivery of Salmon Calcitonin Dry Powders Containing Absorption Enhancers in Rats," <i>Pharm. Res.</i> , 13(1):80-83 (1996).		
	BU7	Kohler, D., "Aerosols for Systemic Treatment" <i>Lung</i> , Suppl: pp. 677-684 (1990).		
M	BV7	Komada, F. et al., Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung," <i>J. Pharm. Sci.</i> , 83(6): 863-867 (June, 1994).		
	BW7	This reference number intentionally left blank.		
M	BX7	Kricheldorf, H.R. "α-Aminoacid-N-Carboxy-Anhydrides and Related Heterocycles," Springer-Verlag, Berlin (1987).		
	BY7	Kwok, K.K., et al., "Production of 5-15 μm Diameter Alginate Polylysine Microcapsules by an Air Atomization Technique," <i>Pharm. Res.</i> , 8(3):341-344 (1991).		
	BZ7	Lai, Y-L., et al., "Sustained Bronchodilation with Isoproterenol Poly(Glycolide-co-Lactide) Microspheres," <i>Pharm. Res.</i> , 10(1):119-125 (1993).		
	BR8	Lai, W.C., et al., "Protection Against <i>Mycoplasma Pulmonosis</i> Infection by Genetic Vaccination," <i>DNA and Cell Biology</i> , 14(7):643-651 (1995).		
	BS8	Landahl, "On The Removal of Air-borne Droplets by The Human Respiratory Tract: I. The Lung," <i>Bull. Math. Biophys.</i> , 12:43-56 (1950).		
	BT8	Langer, R., "New Methods of Drug Delivery", <i>Science</i> , 249:1527-1533 (1990).		
M	BU8	Le Corre, P., et al., "Preparation and Characterization of Bupivacaine-Loaded Polylactide and Polylactide-Co-Glycolide Microspheres," <i>Int. J. of Pharmaceutics</i> , 107:41-49 (1994).		
EXAMINER		DATE CONSIDERED 2/12/04		

PTO-1449 REPRODUCED

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M	BV8	Leone-Bay, A., et al., "Microsphere Formation in a Series of Derivatized α -Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon calcitonin," <i>J. of Med. Chem.</i> , 38(21):4257-4262 (1995).
M	BW8	Liu, F., et al., "Pulmonary Delivery of Free and Liposomal Insulin," <i>Pharm. Res.</i> 10(2):228-232 (1993).
M	BX8	Liu, W.R., et al., "Moisture-Induced Aggregation of Lyophilized Proteins in the Solid State," <i>Biotechnol. and Bioeng.</i> , 37:177-184 (1991).
	BY8	This reference number intentionally left blank.
M	BZ8	Martonen, T.B., "Mathematical Model for the Selective Deposition of Inhaled Pharmaceuticals," <i>J. of Pharm. Sci.</i> , 82(12):1191-1198 (1993).
	BR9	Masinde, L.E., and Hickey, A.J., "Aerosolized Aqueous Suspensions of Poly(L-Lactic Acid) Microspheres," <i>Int. J. of Pharmaceutics</i> , 100:123-131 (1993).
	BS9	Mathiowitz, E., et al., "Novel Microcapsules for Delivery Systems," <i>Reactive Polymers</i> , 6:275-283 (1987).
	BT9	Mathiowitz, E., et al., "Polyanhydride Microspheres. IV. Morphology and Characterization of Systems Made by Spray Drying," <i>J. of Appl. Polymer Sci.</i> 45:125-134 (1992).
	BU9	Mathiowitz, E., et al., "Morphology of Polyanhydride Microsphere Delivery ASystems," <i>Scanning Microscopy</i> , 4(2):329-340 (1990).
	BV9	Mathiowitz, E., and R. Langer, "Polyanhydride Microspheres as Drug Carriers I. Hot-Melt Microencapsulation," <i>J. of Controlled Release</i> 5:13-22 (1987).
	BW9	Mathiowitz, E., et al., "Polyanhydride Microspheres as Drug Carriers. II. Microencapsulation by Solvent Removal," <i>J. of Appl. Polymer Sci.</i> , 35:755-774 (1988).
M	BX9	Ménache, M.G., et al., "Particle Inhalability Curves for Humans and Small Laboratory Animals," <i>Annals of Occupational Hygiene</i> , 39(3):317-328 (1995).
	BY9	This reference number intentionally left blank.
M	BZ9	Morimoto, Y., and Adachi, Y., "Pulmonary Uptake of Liposomal Phosphatidylcholine Upon Intratracheal Administration to Rats," <i>Chem. Pharm. Bull.</i> 30(6):2248-2251 (1982).
M	BR10	Mulligan, R.C., "The Basic Science of Gene Therapy", <i>Science</i> , 260:926-932 (1993).
	BS10	This reference number intentionally left blank.
	BT10	This reference number intentionally left blank.
M	BU10	Newman, S.P., "Therapeutic Inhalation Agents and Devices," <i>Inhalation Therapy</i> , 76(5):194-207 (1984).

EXAMINER



DATE CONSIDERED

2/12/04

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M	BV10	Newman, S.P., "Aerosol Deposition Considerations in Inhalation Therapy," Chest, 88(2):152S-160S (1985).
	BW10	Niven, R.W., et al., "The Pulmonary Absorption of Aerosolized and Intratracheally Instilled rhG-CSF and monoPEGylated rhG-CSF," Pharm. Res., 12(9):1343-1349 (1995).
	BX10	Niven, R.W., et al., "Solute Absorption From the Airways of the Isolated Rat Lung. III. Absorption of Several Peptidase-Resistant, Synthetic Polypeptides: Poly(2-Hydroxyethyl)-Aspartamides," Pharm. Res., 7(10):990-994 (1990).
	BY10	Niwa, T., et al., "Aerosolization of Lactide/Glycolide Copolymer (PLGA) Nanospheres for Pulmonary Delivery of Peptide-Drugs," Yakugaku Zasshi, 115(9):732-741 (1995).
	BZ10	Ogiwara, M., "Clearance and Maximum Removal Rate of Liposomes in Normal and Impaired Liver of Rat," Gastroenterologia Japonica, 19(1):34-40 (1984).
M	BR11	Okumura, K., et al., "Intratracheal Delivery of Insulin. Absorption from Solution and Aerosol by Rat Lung," Int. J. Pharmaceutics, 88:63-73 (1992).
	BS11	This reference number intentionally left blank.
M	BT11	Patton, J.S., et al., "Bioavailability of pulmonary delivered peptides and proteins: α -interferon, calcitonins and parathyroid hormones," J. Controlled Release, 28:79-85 (1994).
	BU11	Pavia, D., "Lung Mucociliary Clearance". In Aerosols and the Lung: Clinical and Experimental Aspects, Clarke, S.W. and Pavia, D., eds. (Butterworths, London), pp. 127-155, (1984).
	BV11	Peart, J. et al., "Multicomponent Particle Interactions in Dry Powder Aerosols," J. Pharm. Res. 14(11 Suppl):p S142-S143 (November 1997).
	BW11	Pinkerton, K.E., et al., "Aerosolized Fluorescent Microspheres Detected in the Lung Using Confocal Scanning Laser Microscopy", Microscopy Res. and Tech., 26:437-443 (1993).
	BX11	Rudt, S., and R.H. Muller, "In Vitro Phagocytosis Assay of Nano- and Microparticles by Chemiluminescence. I. Effect of Analytical Parameters, Particle Size and Particle Concentration," J. Contr. Rel., 22:263-271 (1992).
	BY11	Rudt, S., et al., "In Vitro Phagocytosis Assay of Nano- and Microparticles by Chemiluminescence. IV. Effect of Surface Modification by Coating of Particles with Poloxamine and Antarox CO on the Phagocytic Uptake", J. of Contr. Rel. 25:123-132 (1993).
	BZ11	Ruffin, R.E., et al., "The Preferential Deposition of Inhaled Isoproterenol and Propranolol in Asthmatic Patients," Chest 80(6):904-907 (1981).
	BR12	Sela, M., et al., "Multichain Polyamino Acids," J. Am. Chem. Soc., 78:746-751 (1956).
M	BS12	Smith, A.L., and B. Ramsey, "Aerosol Administration of Antibiotics," Respiration, 62(suppl 1):19-24 (1995).

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED

**SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT
David A. Edwards, et al.

FILING DATE
March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

m	BT12	Smith, P.L., "Peptide Delivery via the Pulmonary Route: A Valid Approach for Local and Systemic Delivery," <i>J. of Contr. Rel.</i> , 46:99-106 (1997).
	BU12	Strand, S.E., and L. Bergqvist, "Radiolabeled Colloids and Macromolecules in the Lymphatic System," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 6(3):211-238 (1989)
	BV12	Swift, D., "The Oral Airway - A Conduit or Collector for Pharmaceutical Aerosols?" <i>Respiratory Drug Delivery IV</i> , 187-195 (1994).
	BW12	Tabata, Y., et al., "Controlled Delivery Systems for Proteins Using Polyanhydride Microspheres," <i>Pharm. Res.</i> 10(4):487-496 (1993).
	BX12	Tabata, Y., and Y. Ikada, "Effect of Surface Wettability of Microspheres on Phagocytosis," <i>J. of Colloid and Interface Sci.</i> , 127(1):132-140 (1989).
	BY12	Tabata, Y., and Y. Ikada, "Macrophage Phagocytosis of Biodegradable Microspheres Composed of L-lactic Acid/glycolic Acid Homo- and Copolymers," <i>J. of Biomed. Mater. Res.</i> , 22:837-858 (1988).
	BZ12	Tabata, Y., and Ikada, Y., "Effect of Size and Surface Charge of Polymer Microspheres on Their Phagocytosis by Macrophage," <i>J. Biomed. Mater. Res.</i> , 22:837-843 (1988).
	BR13	Taburet, A.M., and Schmit, B., "Pharmacokinetic Optimisation of Asthma Treatment," <i>Clin. Pharmacokinet.</i> 26(5):396-418 (1994).
	BS13	Tansey, I.P., "The Challenges in the Development of Metered Dose Inhalation Aerosols Using Ozone-Friendly Propellants," <i>Spray Technol. & Market</i> , 4:26-29 (1994).
	BT13	Timsina, M.P., et al., "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers," <i>Int. J. of Pharm.</i> , 101:1-13 (1994).
m	BU13	Turner, J.R., and S.V. Hering, "Greased and Oiled Substrates as Bounce-Free Impaction Surfaces," <i>J. Aerosol Sci.</i> , 18(2):215-224 (1987).
	BV13	This reference number intentionally left blank.
m	BW13	Wall, D.A., "Pulmonary Absorption of Peptides and Proteins," <i>Drug Delivery</i> , 2:1-20 (1995).
	BX13	Warheit, D.B., and Hartsky, M.A., "Role of Alveolar Macrophage Chemotaxis and Phagocytosis in Pulmonary Clearance to Inhaled Particles: Comparisons Among Rodent Species," <i>Microscopy Res. and Tech.</i> , 26:412-422 (1993).
	BY13	Weiner, Norman et al., "Liposomes as a Drug Delivery System," <i>Drug Development and Industrial Pharmacy</i> , 15(10):1523-1554 (1989).
	BZ13	Wheatley, M.A., et al., "Contrast Agents for Diagnostic Ultrasound: Development and Evaluation of Polymer-Coated Microbubbles," <i>Biomaterials</i> 11:713-717 (1990).
✓	BR14	Wichert, B., and Rohdewald, P., "Low Molecular Weight PLA: A Suitable Polymer for Pulmonary Administered Microparticles?," <i>J. Microencapsulation</i> , 10(2):195-207 (1993).

EXAMINER

DATE CONSIDERED

2/12/04

PTO-1449 REPRODUCED

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

April 2, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-008

APPLICATION NO.
09/822,716

APPLICANT

David A. Edwards, et al.

FILING DATE

March 30, 2001

CONFIRMATION NO.
7248

GROUP
1615

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M

BS14

Wong, M., and Suslick, K.S., "Sonochemically Produced Hemoglobin Microbubbles," *Mat. Res. Soc. Symp. Proc.*, 372:89-95 (1995).

BT14

Zanen, P., et al., "The Optimal Particle Size for β -adrenergic Aerosols in Mild Asthmatics", *Int. J. of Pharm.*, 107:211-217 (1994).

BU14

Zanen, P., et al., "The Optimal Particle Size for Parasympatholytic Aerosols in Mild Asthmatics", *Int. J. of Pharm.*, 114:111-115 (1995).

BV14

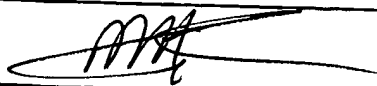
Zeng, X.M., et al., "The Controlled Delivery of Drugs to the Lung," *Int. J. of Pharm.*, 124:149-164 (1995).

M

BW14

Zeng, X.M., et al., "Tetrandrine Delivery to the Lung: The Optimisation of Albumin Microsphere Preparation by Central Composite Design," *Int. J. of Pharm.*, 109:135-145 (1994).

EXAMINER



DATE CONSIDERED

2/12/04